zimmer

MAR 10 2000

K994286

P.O. Box 708
Warsaw, IN 46581-0708
219 267-6131

By 2/2

Summary of Safety and Effectiveness

- **Submitted By:**

  Zimmer, Inc.
  P.O. Box 708
  Warsaw, Indiana 46581-0708
  219-267-6131

- **Contact Person:**

  Karen Cain
  Senior Regulatory Affairs Associate
  Telephone: 219/372-4219
  Fax: 219/372-4605

- **Date:**

  December 17, 1999

- **Trade Name:**

  ZMR™ Hip System-Porous Revision

- **Common Name:**

  Femoral Hip Prosthesis

- **Classification Name:**

  Hip joint metal/polymer semiconstrained uncemented prosthesis

- **Predicate Devices:**

  - *Impact*™ Modular Total Hip System, manufactured by Biomet, K921274, cleared February 15, 1994
  - Coated *ZT*™ Proximal Sleeve of the *S-ROM*™ Total Hip System, manufactured by Johnson & Johnson (previously Joint Medical Products Corporation), K934412, cleared June 3, 1994
  - Mallory-Head Modular Porous Series, manufactured by Biomet, K921274, cleared February 15, 1994

Summary of Safety and Effectiveness
(Continued)

- *ZMR*™ Hip System-Revision Taper, manufactured by Zimmer, K992667, cleared October 27, 1999

- **Device Description**

  The *ZMR* Porous Revision Hip Prosthesis is a femoral stem manufactured from *Tivanium*® (Ti-6Al-4V) Alloy and intended for cementless use in revision hip arthroplasty. This device has two modular junctions: a head/neck junction and a midstem junction. Three components are intraoperatively assembled to construct the device: a proximal segment or "body," a distal stem, and a compression nut.

- **Intended Use**

  The *ZMR* Porous Revision Hip Prosthesis is intended for revision hip arthroplasty in patients whose bone stock is of poor quality or inadequate for other reconstruction techniques as indicated by deficiencies of the femoral head, neck, or portions of the proximal femur.

- **Comparison to Predicate Devices**

  All hip systems listed above are substantially equivalent to each other and the *ZMR* Porous Revision Hip Prosthesis in that each is intended for cementless fixation into the intramedullary canal for pathological or degenerative conditions involving the femur and/or acetabulum. All predicate devices feature a Morse-type proximal neck taper that mates with a femoral head which, in turn, articulates upon the ultra-high molecular-weight polyethylene (UHMWPE) bearing surface of a total hip or hemi-hip acetabular component. All predicate devices are manufactured from metal alloys that have a history of successful clinical use in orthopaedic applications.

RA11901K.510

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 10 2000

Ms. Karen Cain
Regulatory Affairs Associate
Zimmer, Inc.
P.O. Box 708
Warsaw, Indiana 46581-0708

Re: K994286
Trade Name: ZMR™ Hip System Porous Revision
Regulatory Class: II
Product Code: LPH
Dated: December 17, 1999
Received: December 20, 1999

Dear Ms. Cain:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general control provisions of the Act. The general control provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for James E. Dillard III
Acting Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Exhibit S

510(k) Number (if known K994286

Device Name:

ZMR™ Hip System-Porous Revision Hip Prosthesis

Indications for Use:

The *ZMR* Porous Revision Hip Prosthesis is intended for cementless revision hip arthroplasty in patients whose bone stock is of poor quality or inadequate for other reconstruction techniques as indicated by deficiencies of the femoral head, neck, or portions of the proximal femur.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use
(Per 21 CFR 801.109) (Optional Format 1-2-96)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K994286